DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Zimmer GMBH
Dr. Annemie Rehor Kausch
Senior Specialist Regulatory Affairs
Sulzerallee 8
8404 Winterthur, Switzerland

November 24, 2014

Re: K142403
Trade/Device Name: Anatomical Shoulder™ System/Anatomical Shoulder™ Domelock®/Anatomical Shoulder™ Fracture System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: KWS, PHX, KWT, HSD
Dated: August 25, 2014
Received: August 27, 2014

Dear Dr. Kausch:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
not known

Device Name
Anatomical Shoulder™ System
Anatomical Shoulder™ Domelock®
Anatomical Shoulder™ Fracture System

Indications for Use *(Describe)*
Hemi or Total Arthroplasty Application of the Anatomical Shoulder Humeral Stems and Domelock System

The Anatomical Shoulder Humeral Stems and Domelock System are indicated for
• Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis.
• Avascular necrosis.
• Conditions consequent to earlier operations.
• Omarthrosis.
• Rheumatoid arthritis.
• Revision of shoulder prosthesis.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used in a total shoulder application, the Anatomical Shoulder Pegged and Keeled Glenoids Cemented are intended for cemented use only.

Reverse Application of the Anatomical Shoulder System

• The Anatomical Shoulder Inverse/Reverse System is indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
• The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used with the Anatomical Shoulder Glenoid Fixation, it is intended for uncemented use and requires two screws for fixation.

Fracture Application of the Anatomical Shoulder Fracture System

The Anatomical Shoulder Fracture System is intended for use in prosthetic replacement of the proximal humerus and the glenoid articular surface of the scapula during total-, hemi and fracture shoulder arthroplasty in treatment of the following:
• Complex 3- and 4-part fractures of the proximal humerus with subluxation of the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with loosening of the spongiosa in the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with additional cross split of the head fragment
• Fracture instability after osteosynthesis of 3- and 4-part fracture fragments of the proximal humerus
• Posttraumatic necrosis of the humeral head
• Posttraumatic arthrosis after humeral head fracture

The Humeral Fracture Stems are intended for either cemented or uncemented use. When used in a total shoulder application, the Anatomical Shoulder Pegged and Keeled Glenoids Cemented are intended for cemented use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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Zimmer GmbH
Sulzerallee 8
8404 Winterthur
Switzerland

510(k) Summary

Sponsor:	Zimmer GmbH Sulzerallee 8, P.O. Box 8404 Winterthur, Switzerland
Contact Person:	Annemie Rehor Kausch Senior Specialist, Regulatory Affairs Telephone: +41 58 854 82 61 Fax: + 41 52 244 86 58
Date:	November, 24th 2014
Trade Name:	Anatomical Shoulder™ System Anatomical Shoulder ™ Domelock® Anatomical Shoulder ™ Fracture System
Classification Product Code /	**HSD** – Prosthesis, Shoulder, Hemi-, Humeral, Metallic Uncemented **KWS** – Prosthesis, Shoulder, Semi-Constrained, Metal/Polymer Cemented **KWT** – Prosthesis, Shoulder, Non-Constrained, Metal/Polymer Cemented **PHX** – Shoulder Prosthesis, Reverse Configuration
Device Classification Name:	Shoulder Prosthesis
Regulation Number / Description:	21 CFR § 888.3690 – Shoulder joint humeral (hemishoulder) metallic uncemented prosthesis 21 CFR § 888.3660 – Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR § 888.3650 – Shoulder joint metal/polymer non-constrained cemented prosthesis
Predicate Device:	*Anatomical Shoulder* with Removable Head, manufactured by Zimmer GmbH, K030259, cleared April 24, 2003 *Anatomical Shoulder* Fracture System,

manufactured by Zimmer GmbH, K062029, cleared October 31, 2006)

Device Description:

The *Anatomical Shoulder* System is a modular shoulder prosthesis designed to be used in primary or revision, total or hemi shoulder arthroplasty.

Anatomical Shoulder Humeral Stems are available as either cemented or uncemented designs. Cemented stems are available in longer designs to support revision cases. All Humeral Stems possess a female oval taper geometry, which is the basis for all modularity with compatible mating components. For a hemi or total arthroplasty application, the stems can be combined with the proposed *Anatomical Shoulder Domelock* System, the existing *Anatomical Shoulder* Ball-taper Humeral Head System or the existing *Anatomical Shoulder Bigliani/Flatow* Adaptor. For a reverse application the stems are combined with the existing *Anatomical Shoulder* Inverse/Reverse components.

The *Anatomical Shoulder Domelock* System consists of a Humeral Head which is connected to the *Anatomical Shoulder* Stems using either an adjustable *Domelock* Dome centric including a Ball-taper and Expansion-pin, or a series of fixed-angle T-Domes. The *Domelock* Dome and T-Domes are used to set the orientation of the *Domelock* Humeral Heads. The male oval cone taper of the *Domelock* component is compatible with all Humeral Stems of the Anatomical Shoulder System. The assembled humeral component may be used alone for hemiarthroplasty or combined with the existing glenoid component of the *Anatomical Shoulder* System for total arthroplasty.

The *Anatomical Shoulder* Fracture System consists of a Humeral Fracture Stem and a Humeral Head Fracture including a Fracture Baseplate and a Looking Screw. The *Anatomical Shoulder* Fracture Stem is available as a slim and standard version, with longer stems available for revision surgery. They may be used with or without bone cement where appropriate fixation using cement or via a press-fit is achieved using the correct choice of rasp size. The *Anatomical Shoulder* Humeral Head Fracture offers right and left side-specific versions. The assembled

Anatomical Shoulder Fracture humeral component may be used alone for hemiarthroplasty or combined with the glenoid component of the *Anatomical Shoulder* System for total arthroplasty. The *Anatomical Shoulder* Fracture Stem is also designed to accept the existing *Anatomical Shoulder* Inverse/Reverse components and the existing *Anatomical Shoulder Bigliani/Flatow* Adaptor.

The Humeral Stems and Baseplates are made from *Protasul*-100 (Ti6Al7Nb, ASTM F1295-11). The *Domelock* Humeral Heads, the Fracture Heads and the Fracture Screw are made from *Protasul*-21WF (Co28Cr6Mo, ASTM F1537-11). The *Domelock* head locking mechanism is made from *Protasul*-100 and *Protasul*-64WF (Ti6Al4V, ASTM F136-13). The materials are anticipated to have permanent contact. All components are provided sterile (gamma irradiated) for use implantation in a hospital.

Intended Use:

The *Anatomical Shoulder* System is intended for long-term implantation into the human shoulder joint in primary or revision, total or hemi shoulder arthroplasty. The system is intended to relieve pain and restore function in patients with adequate bone stock to support the prosthesis.

<u>Hemi or Total Arthroplasty Application of the *Anatomical Shoulder* Humeral Stems and *Domelock* System</u>

The *Anatomical Shoulder* Humeral Stems and *Domelock* System are indicated for

- Advanced wear and tear of the shoulder joint resulting from degenerative, posttraumatic or rheumatoid arthritis.
- Avascular necrosis.
- Conditions consequent to earlier operations.
- Omarthrosis.
- Rheumatoid arthritis.
- Revision of shoulder prosthesis.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used in a total shoulder application, the *Anatomical Shoulder*

Pegged and Keeled Glenoids Cemented are intended for cemented use only.

Reverse Application of the Anatomical Shoulder System

• The *Anatomical Shoulder* Inverse/Reverse System is indicated for primary, fracture or revision total shoulder replacement for the relief of pain and significant disability due to gross rotator cuff deficiency.
• The patient's joint must be anatomically and structurally suited to receive the selected implants and a functional deltoid muscle is necessary to use the device.

The Humeral Stems Cemented are intended for cemented use and the Humeral Stems Uncemented are intended for uncemented use. When used with the *Anatomical Shoulder* Glenoid Fixation, it is intended for uncemented use and requires two screws for fixation.

Fracture Application of the *Anatomical Shoulder* Fracture System

The *Anatomical Shoulder* Fracture System is intended for use in prosthetic replacement of the proximal humerus and the glenoid articular surface of the scapula during total-, hemi and fracture shoulder arthroplasty in treatment of the following:
• Complex 3- and 4-part fractures of the proximal humerus with subluxation of the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with loosening of the spongiosa in the head fragment
• Complex 3- and 4-part fractures of the proximal humerus with additional cross split of the head fragment
• Fracture instability after osteosynthesis of 3- and 4-part fracture fragments of the proximal humerus
• Posttraumatic necrosis of the humeral head
• Posttraumatic arthrosis after humeral head fracture

The Humeral Fracture Stems are intended for either cemented or uncemented use. When used in a total shoulder application, the *Anatomical Shoulder*

	Pegged and Keeled Glenoids Cemented are intended for cemented use only.
Comparison to Predicate Device:	The proposed devices are line extensions to the predicate devices. They share the same indications for use/intended use, utilize the same materials and manufacturing processes, and have similar technical features as their predicates.
Performance Data (Nonclinical and/or Clinical):	The results of non-clinical performance testing and analyses demonstrate that the devices are safe and effective and substantially equivalent to the predicate devices. Performance testing and/or analyses included: 1. Literature review 2. Morphological and Range of Motion Analysis (ASTM F1378-12) 3. Finite Element Analysis and Fatigue testing (ASTM F1378-12) 4. Connection strength testing (ASTM F2009-00) 5. Humeral stem fixation testing 6. Joint Contact stresses analysis Clinical Performance and Conclusions: Clinical data and conclusions were not needed to demonstrate substantial equivalence.